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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,145	09/29/2003	Doug A. Kaufmann	700725-1002	4264
38406	7590	11/14/2005		
MICHAEL A. O'NEIL, P.C. 5949 SHERRY LANE, SUITE 820 DALLAS, TX 75225			EXAMINER WEDDINGTON, KEVIN E	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 11/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/674,145

Applicant(s)

KAUFMANN, DOUG A.

Examiner

Kevin E. Weddington

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-62 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12-22-03; 2-22-05</u> . | 6) <input type="checkbox"/> Other: _____  |

Claims 1-62 are presented for examination.

Applicant's information disclosure statements filed December 22, 2003 and February 22, 2005 have been received and entered.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating breast cancer, cancer of the lymphoma and prostate cancer, does not reasonably provide enablement for other types of cancers such as lung cancer and ovarian cancer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per factors indicated in the decision In re Wands, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation.

The factors include:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention

- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice that instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to a method of treating a mammal having cancer comprising administering to said mammal a formulation in an amount, at a frequency, and for a duration effective to reduce or eliminate said cancer, said formulation comprising an anti-fungal agent.

The relative skill of those in the art is generally that of a Ph.D. or M.D.

The present invention is unpredictable unless experimentation is shown for the anti-fungal agent can treat other types of cancers.

The breadth of the claims

The claims are very broad and inclusive to all types of cancer are treated with the formulation comprising an anti-fungal agent.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are limited to the administration of anti-fungal agents to treat breast cancer, cancer of the lymphoma (large B-cell lymphoma) and prostate cancer.

No working examples showing the anti-fungal formulation can treat other types of cancers such as lung cancer, colon cancer, ovarian cancer or skin cancer.

The quantity of experimentation necessary

Applicants have failed to provide guidance as to how the instant anti-fungal formulation is effective in the treatment of other types of cancers such as ovarian cancer, etc. The level of experimentation needed to determine the other cancers were reduced or eliminated by the administration of the instant anti-fungal formulation is undue. Therefore, undue experimentation would be required to practice the invention as it is claimed in its current scope.

Claims 1-62 are not allowed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 32 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Peehl et al., "Rationale For Combination Ketoconazole/Vitamin D Treatment of Prostate Cancer", Urology, Vol. 58, Issue, Supplement 2A, pp. 123-126, 2001. or

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Mann, D. Antifungal agent lower PSA levels, study finds. May 1, 1997. p6. Medical Tribune of PTO-1449.

Peehl et al. teach ketoconazole, alone or in combination with vitamin D, is effective in the treatment of prostate cancer. (See the abstract)

Mann, D. teaches Nizoral ® (ketoconazole), an anti-fungal agent, lowered the PSA levels in men with prostate cancer.

Clearly, the two individual references teach well-known ant-fungal agent, ketoconazole, possess anti-tumor or anti-cancer activity; therefore, the two individual references anticipates the applicant's instant invention.

Claims 1, 2, 32 and 33 are not allowed.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Peehl et al., "Rationale For Combination Ketoconazole/Vitamin D Treatment of Prostate Cancer", Urology, Vol. 58, Issue, Supplement 2A, pp. 123-126, 2001. or Charnon, Jody. Selenium supplements reportedly lower the risk of some cancers in humans. Medical Tribune. Vol. 38, Number 2. Jan 23, 1997 and Costantini et al. Etiology and Prevention of Prostate Cancer: Hope at Last. Fungalbionics series.

Johann Reiedrich Oberlin Verlag. Freiburg, Germany. 1998/1999. pp. 320-323 of PTO-1449.

Peehl et al. was discussed above supra for the administration of ketoconazole, alone or in combination with vitamin D for the treatment of prostate cancer. Note on page 124, under the section ANTITUMOR EFFECTS OF VITAMIN D, states that vitamin D has been shown to inhibit growth, increase differentiation, and decrease invasion of prostatic cells in culture.

Charnon teaches selenium supplements are used to lower the risk of prostate, lung and colorectal cancer. The Costantini et al. reference is cited to show that selenium is an anti-fungal agent used to treat prostate cancer.

Clearly, the cited references anticipates applicant's instant invention.

Claims 17 and 48 are not allowed.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-16, 18-31, 34-47 and 49-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peehl et al., Mann, D., Charnon, J., and Costantini et al. in

view of Medical Tribune, June 20, 1996, Vol. 32, issue 12 of PTO-1449 (applicant's submission).

The four primary reference, each individually, teach anti-fungal agents possessing anti-tumor or anti-cancer properties.

The instant invention differs from the cited references in that the cited references do not teach the a low carbohydrate diet is administered along with the administration of the anti-fungal agent. However, the secondary reference, Medical Tribune, teaches high carbohydrate diet increase the risk of cancer (breast). Clearly, one skilled in the art would have assumed the lowering of carbohydrates in ones diet would lower the risk of cancer in the absence of evidence to the contrary.

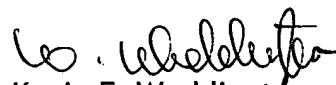
Claims 3-16, 18-31, 34-47 and 49-62 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin E. Weddington whose telephone number is (571)272-0587. The examiner can normally be reached on 11:00 am-7:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Kevin E. Weddington  
Primary Examiner  
Art Unit 1614

K. Weddington  
November 8, 2005